

PACKAGE LEAFLET: INFORMATION FOR THE USER

Disipal® 50mg Tablets

(orphenadrine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Disipal® 50mg Tablets but will be referred to as Disipal Tablets throughout this leaflet.

In this leaflet:

1. What Disipal Tablets are and what they are used for
2. Before you take Disipal Tablets
3. How to take Disipal Tablets
4. Possible side effects
5. How to store Disipal Tablets
6. Further information

1. WHAT DISIPAL TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in Disipal Tablets belongs to the group of medicines called anticholinergic agents. Disipal Tablets are used in the treatment of all forms of Parkinson's disease, a condition which can cause uncontrollable trembling of the hands, and other difficulties of movement, for example in standing or walking. Anticholinergic agents are also used when other medicines have caused these problems.

2. BEFORE YOU TAKE DISIPAL TABLETS

Do not take Disipal Tablets. Tell your doctor if you:

- are **allergic (hypersensitive)** to orphenadrine or any of the other ingredients of Disipal Tablets (see list in section 6 'Further information')
- have **increased pressure in the eye** (glaucoma).
- have an **enlarged prostate**.
- are **unable to pass water** for any reason.
- have a **blockage** in your **digestive system** or any **stomach disorders**.
- suffer from a **rare inherited disease** where the **breakdown of haemoglobin** (a pigment in the red blood cells) is affected (porphyria).
- suffer from **involuntary movements of the face or body** (tardive dyskinesia). Your doctor will take this into consideration before prescribing the tablets for you.

- suffer from a **rare hereditary problem** of fructose and galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.

Disipal Tablets should not be given to children.

Take special care with Disipal Tablets

Tell your doctor if you:

- suffer from heart disease
- suffer from liver disorders
- suffer from kidney disorders
- have difficulties passing water

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking other anticholinergic agents at the same time as Disipal Tablets, this can lead to an increase in dry mouth and difficulties in passing water. Your doctor or pharmacist will be able to advise you whether any of the medicines you are taking fall into this category.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Do not use Disipal Tablets during pregnancy or if you are breast-feeding, unless clearly necessary.

Driving and using machines

Do not drive or use any tools or machines if you feel dizzy or have blurred vision whilst taking Disipal Tablets.

Important information about some of the ingredients of Disipal Tablets

This medicine contains sucrose. If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicine. The colours tartrazine (E102), sunset yellow (E110) and amaranth (E123) used in the sugar coat may cause allergic reactions (see section 6 for the list of ingredients).

3. HOW TO TAKE DISIPAL TABLETS

Always take Disipal Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

The usual dose for adults and the elderly is three tablets daily in divided doses. Your doctor may increase this dose, if necessary, by one tablet every two to three days up to a maximum of eight tablets in a day. Usually you will need long term treatment with Disipal Tablets.

Use in children

Disipal Tablets should not be given to children.

If you take more Disipal Tablets than you should

Taking more Disipal Tablets than have been prescribed could be dangerous. If you, or anyone else, should accidentally take more tablets than prescribed, you must phone your doctor or go to a hospital casualty department **immediately**.

If you forget to take Disipal Tablets

Take the forgotten dose as soon as you remember. If it is time for your next dose skip the dose you missed and just continue to follow the dosing schedule as usual. Do not take a double dose to make up for a forgotten one.

If you stop taking Disipal Tablets

If you are to stop taking Disipal Tablets then your doctor will make sure that the dose is gradually reduced over a number of days. You should not stop taking the tablets unless you have been told to do so by your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Disipal Tablets can cause side effects, although not everybody gets them. If you are elderly you may be more likely to get side effects.

Uncommon (fewer than 1 in 100 patients)
allergic reactions may occur while on treatment with Disipal Tablets. Signs of allergy include: rash – wheezing – breathlessness - swollen eyelids - face or lips and in extreme cases collapse. If you get any of these symptoms soon after taking Disipal Tablets, do not take any more. Tell a doctor immediately and take the packaging and this leaflet with you.

Other possible side effects:

Common (fewer than 1 in 10 patients)

- dry mouth, stomach upsets
- dizziness
- difficulty in seeing clearly

Uncommon (fewer than 1 in 100 patients)

- rapid heart beat
- changes of mood such as highly elevated mood, confusion, sleepiness, hallucinations, difficulty in sleeping, nervousness, seizure (fits)
- difficulty in passing water

Rare (fewer than 1 in 1000 patients)

- memory disturbance

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DISIPAL TABLETS

- Keep out of the sight and reach of children
- Store at room temperature (15°C-25°C).
- Do not take your tablets after the expiry date which is stated on the carton/blister label after 'Exp'. The expiry date refers to the last day of that month.
- Remember if your doctor tells you to stop taking this medicine; return any unused tablets to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- Medicines should not be disposed of via waste water or house hold waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- If your tablet becomes discoloured or show any signs of deterioration, seek the advice of your pharmacist.

6. FURTHER INFORMATION

What Disipal Tablets contain

Each tablet contains 50mg orphenadrine hydrochloride. Other ingredients are microcrystalline cellulose, maize starch granulated, stearic acid, magnesium stearate, silicon dioxide. Excipients for sugar-coating are shellac, acacia, talc, beta-carotene E160a, sucrose.

What Disipal Tablets look like and contents of the pack

Disipal are round, yellow, sugar coated tablets with no markings.

Tablets come in blister pack.

Disipal Tablets are available in packs of 50 tablets.

Manufactured by: Mipharm S.p.A., Via B.Quaranta, 12-20141, Milan, Italy.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Disipal® 50mg Tablets

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PL No: 18799/2162

Leaflet date: 16.06.2015

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Orphenadrine hydrochloride 50mg Tablets

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The name of your medicine is Orphenadrine hydrochloride 50mg Tablets but will be referred to as Orphenadrine throughout this leaflet.

In this leaflet:

1. What Orphenadrine Tablets are and what they are used for
2. Before you take Orphenadrine Tablets
3. How to take Orphenadrine Tablets
4. Possible side effects
5. How to store Orphenadrine Tablets
6. Further information

1. WHAT ORPHENADRINE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in Orphenadrine Tablets belongs to the group of medicines called anticholinergic agents. Orphenadrine Tablets are used in the treatment of all forms of Parkinson's disease, a condition which can cause uncontrollable trembling of the hands, and other difficulties of movement, for example in standing or walking. Anticholinergic agents are also used when other medicines have caused these problems.

2. BEFORE YOU TAKE ORPHENADRINE TABLETS

Do not take Orphenadrine Tablets. Tell your doctor if you:

- are **allergic (hypersensitive)** to orphenadrine or any of the other ingredients of Orphenadrine Tablets (see list in section 6 'Further information')
- have **increased pressure in the eye** (glaucoma).
- have an **enlarged prostate**.
- are **unable to pass water** for any reason.
- have a **blockage** in your **digestive system** or any **stomach disorders**.
- suffer from a **rare inherited disease** where the **breakdown of haemoglobin** (a pigment in the red blood cells) is affected (porphyria).
- suffer from **involuntary movements of the face or body** (tardive dyskinesia). Your doctor will take this into consideration before prescribing the tablets for you.

- suffer from a **rare hereditary problem** of fructose and galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.

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Taking other medicines

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Driving and using machines

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